



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,925	12/28/2001	Richard N. Ellson	7610-0040.20	5528

23980 7590 02/23/2005

REED INTELLECTUAL PROPERTY LAW GROUP
800 MENLO AVENUE, SUITE 210
MENLO PARK, CA 94025

EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
----------	--------------

1641

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/040,925

Applicant(s)

ELLSON ET AL.

Examiner

Nelson Yang

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-60 is/are pending in the application.
- 4a) Of the above claim(s) 6-11, 31, 33, 34, 45, 46 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 12-30, 32, 35-44, 47 and 49-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 3, 14, 52, 56, and 58 is acknowledged and has been entered.
2. Applicant's cancellation of claims 2 and 61-82 is acknowledged and has been entered.
3. Claims 1 and 3-60 are currently pending.
4. Claims 6-11, 31, 33-34, 45-46, 48 have been withdrawn.

Election/Restrictions

5. Applicant's election with traverse of claims 61-64 (groups II and III) and claims 65-82 (groups IV and V) in the reply filed on August 16, 2004 is acknowledged. The traversal is on the ground(s) that claims 61-64 should be kept together as they recite the attachment of molecular moieties to a substrate, while claims 65-82 should be kept together because they set forth the assaying of a sample. As the traversed claims have been cancelled, however, the restriction with respect to these claims is moot.
6. The requirement is still deemed proper and is therefore made FINAL.

Rejections Withdrawn

7. Applicant's arguments, see p. 16-18, filed August 16, 2004, with respect to the rejection of claims 1-5, 12-30, 32, 35-44, 47, 49-60 are rejected under 35 U.S.C. 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 1-5, 12-30, 32, 35-44, 47, 49-60 are rejected under 35 U.S.C. 112, second paragraph, has been withdrawn.

Claim Rejections - 35 USC § 102

Art Unit: 1641

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-5, 12-30, 32, 49-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Ward et al [US 4,687,732].

With respect to claims 1, 3-5, 19, 52, 58, Ward et al teach a visualization polymer comprising multiple visualization units covalently linked together by polymerization or a coupling agent, where each unit of the polymer possesses at least one visualization site (column 4, lines 19-29) and can be used to detect minute quantities of target molecules, including blood, lymph, urine, feces, organ tissue, microorganisms, plant tissue, cultured cells, hybrid cells, cells with recombinant DNA, synthetic mixtures of polypeptides, immobilized enzyme systems, synthesized DNA and other biological material (column 20, lines 34-45). The measurement may be accomplished by production of a readily identifiable substrate product or production of a spectroscopic signal as well as other, similar types of nondestructive quantitative analytic methods for measurement. This can be done by enzyme units that catalyze reaction of substrates to produce colored, fluorescent, luminescent, electron dense or radioactive properties (column 9, lines 10-23). These properties would be capable of being detected even after removal of the condition, and thus would be detectable for at least one minute, 1 hour afterwards, and could be considered substantially permanently detectable, as they are the indicator responses disclosed by applicant as seen on p. 6, lines 25-30 of the specification.

Art Unit: 1641

10. With respect to claims 12-14, 53-55, Ward et al teach that the reactions were performed in a 5 mg/ml solution of DSS in dimethylformamide (column 24, lines 1-10), where the pH of the solution is performed at a pH of 7.6 (column 24, line 4). In this embodiment the purity of conditions would be a formamide concentration and a pH condition.

11. With respect to claim 15, sodium azide was added to a final concentration of 0.02 % (W/V) (column 24, lines 33-37).

12. With respect to claims 16-18, 26-29, 59, 60 Ward et al teach that chemical groups may be used for direct bonding or indirect linking with the coupling agent (column 10, lines 25-30). Reactions on the device can be incubated at temperatures from ambient to about 37°C for periods such as 5 minutes to 18 hrs to cause conjugation (column 20, lines 60-66). Addition of visualization polymer or its complex under similar conditions will then provide visualization (column 20, lines 67-68).

Furthermore, it should be noted that the step of exposing the device to a condition is considered a method step and therefore would not have any patentable weight in product claims.

13. With respect to claim 20-24, the signal can comprise a fluorescent group, a dye, a luminescent group or an electron dense group (column 7, lines 19-25) or quench a colored, fluorescent or luminescent substrate (column 17, lines 20-22).

14. With respect to claim 25, the tagged units may be directly utilized as tools for spectroscopic measurement, such that when placed in a spectrometer, a spectrographic change will occur (column 9, lines 10-23).

15. With respect to claims 30, 32, 49-51, 56, the detecting agents may be biotin or imino biotin labeled polynucleotide detecting agents (column 19, lines 60-65).

Art Unit: 1641

16. With respect to claim 35, the probes are arranged in arrays of strips (fig. 1).
17. With respect to claim 57, the condition can be hybridization conditions (column 26, lines 3-36).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al [US 5,874,214] and further in view of Rava et al [US 5,545,531].

With respect to claims 36-39, Ward et al teach a visualization polymer comprising multiple visualization units covalently linked together by polymerization or a coupling agent, where each unit of the polymer possesses at least one visualization site (column 4, lines 19-29) and can be used to detect minute quantities of target molecules, including blood, lymph, urine, feces, organ tissue, microorganisms, plant tissue, cultured cells, hybrid cells, cells with recombinant DNA, synthetic mixtures of polypeptides, immobilized enzyme systems, synthesized DNA and other biological material (column 20, lines 34-45), as discussed above. Ward et al fails to teach the concentration of probes per square centimeter of substrate surface.

Rava et al, however, teach the use of probe arrays with sizes of .25 mm² having different amounts of addressable features (probes), including at least 100, 1,000, 100,000, and 1,000,000 addressable features (column 9, lines 10-26). Rava et al further teach that these arrays allow for

Art Unit: 1641

much higher throughput of test samples, greatly improving the efficiency of performing assays on biological chips (column 4, lines 25-34).

Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Therefore it would also have been obvious in the device of Ward et al to have arrays with different densities of probes, including at least 100, 1,000, 100,000, and 1,000,000 probes/cm² substrate surface, as suggested by Rava et al, in order to improve the efficiency of performing assays on biological chips.

20. Claims 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al [US 5,874,214] and further in view of Nova et al [US 5,741,462].

With respect to claims 40-42, Ward et al teach a visualization polymer comprising multiple visualization units covalently linked together by polymerization or a coupling agent, where each unit of the polymer possesses at least one visualization site (column 4, lines 19-29) and can be used to detect minute quantities of target molecules, including blood, lymph, urine, feces, organ tissue, microorganisms, plant tissue, cultured cells, hybrid cells, cells with recombinant DNA, synthetic mixtures of polypeptides, immobilized enzyme systems, synthesized DNA and other biological material (column 20, lines 34-45), as discussed above. Ward et al fails to teach that the substrate comprises a medium capable of containing electronic information

Nova et al, however, teach a memory device having non-volatile memory means (column 5, lines 1-10). Nova et al further teach that the memory device allows for the identification of

Art Unit: 1641

molecules or biological particles, either by their process of preparation, their identity, their batch number, category, physical or chemical properties, combinations of any of such information, or other identifying information (column 5, lines 22-30).

Therefore it would have been obvious in the device of Ward et al to have a memory device, as suggested by Nova et al, to allow for the identification of molecules or biological particles.

21. With respect to claim 43-44, the device is coated with at least one layer of material disposed on an outer surface, upon which molecules or biological particles are retained (column 5, lines 10-13). Therefore, the device would be located on the surface of the layer opposite the surface upon which the molecules or biological particles are retained.

Response to Arguments

22. Applicant's arguments with respect to claims 1, 3-5, 12-30, 32, 35-44, 47, 49-60 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

23. No claims are allowed.

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1641

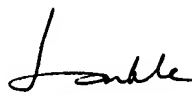
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
Art Unit 1641


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

02/18/05